

K041971

MAY 20 2005

**Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act**

October 30, 2003

1. General Provisions

Common/Usual Name: RADIATION TREATMENT PLANNING SYSTEM

Proprietary Name: WIMRT

Applicant Name and Address:

Prodigm Group, Inc.
19078 Chaparral Drive
Penn Valley, CA 95946
Telephone: 530-432-5846
Fax: 530-432-2882

2. Name of Predicate Devices:

(1)

Manufacturer	K Number
NOMOS Corvus Inverse Planning System	K940663
Varian Helios Inverse Planning Module	K984532
ADAC Laboratories P3IMRT Module	K002237

¹

Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seq. (1977).

3. Classification

This device is classified as a class II device according to 21 CFR 892.5050 .

4. Performance Standards

Performance standards for Brachytherapy applicators have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description

The TOPSLANE product ARTP with WIMRT is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. ARTP with WIMRT is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray energies from 1 to 25MV, as well as Cobalt-60, and electron energies from 1 to 25 MeV.

6. Biocompatibility

No new issues of biocompatibility are raised with regard to this device.

7. Summary of Substantial Equivalence

This device is similar in design and construction, and has the same intended use and performance characteristics to the predicate device. It utilizes materials that are already in use in other medical devices. No new issues of safety or effectiveness are introduced by using this device.

Table 1
Comparison of WIMRT Module
to the Predicate Devices

Specification	WIMRT Module	ADAC P3IMRT Module	Varian Helios Inverse Planning Module	NOMOS Corvus Inverse Planning System
K Number	This filing	K002237	K984532	K940663
Application (Use)	Inverse Planning	Inverse Planning	Inverse Planning	Inverse Planning
Imaging Modalities Supported	CT,MR, PET-Spec	CT, MR, PET-Spec	CT, MR. PET-Spec	CT, MR, PET-Spec
Dose Calculation Algorithm	Super-position Convolution	Super-position Convolution	Pencil Beam Convolution	Finite Sum Pencil Beam
Optimization Engine	Simulated Annealing and Descending Gradient	Collapsing Gradient Cone	Descending Gradient	Simulated Annealing and Descending Gradient
IMRT Modalities Supported	Sliding Window and Step and Shoot	Step and Shoot	Sliding Window and Step and Shoot	Step and Shoot
Operating System	Windows	UNIX	Windows 2000/Windows NT	NeXT Step and UNIX
Image Registration	Automatic	Manual and Automatic	Manual and Automatic	Manual and Automatic
Automated Planning	Yes	Yes via Scripts	Yes via Templates	No
Inhomogeneity Corrections	Yes	Yes	Yes	Yes
Forward IMRT via Field within a Field technique	Yes	Yes	Yes	No
Forward IMRT via MLC Based compensators	Yes	No	Yes	No



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2005

Lee Potts
President
Prodigm Group, Inc.
19078 Chaparral Drive
PENN VALLEY CA 95946

Re: K041971
Trade/Device Name: WIMRT
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: April 25 2005
Received: May 2, 2005

Dear Mr. Potts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: *To be assigned* K041971

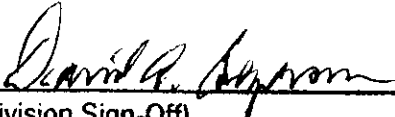
Device Name: WIMRT

Indications for Use:

The TOPSLANE product ARTP with WIMRT is a Radiation Therapy Treatment Planning System for radiation dose planning of patients undergoing external beam treatment in the oncology clinic. ARTP with WIMRT is used to plan radiation treatments with linear accelerators and other similar teletherapy devices with x-ray energies from 1 to 25MV, as well as Cobalt-60, and electron energies from 1 to 25 MeV.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over-The Counter Use: (Per 21 CFR 801.109)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041971